IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

John Barthelow Classen — **Attorney Docket: 61185.00005**

Application No.: 10/081,705 — **Group Art Unit: 1273**

Filed: 02/21/2002 — **Examiner: LEROUX, Etienne Pierre**

Title: ***Computer Algorithms and Methods for Product Safety***

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Declaration of John Barthelow Classen under 37 C.F.R. §1.131

I, John Barthelow Classen declare that:

1. I am the sole named and true inventor of U.S. Patent Appl. 10/081,705, filed February 21, 2002, claiming an effective filing date of February 21, 2001, when U.S. Provisional Application No. 60/270.697 was filed, the content of which was incorporated into the present application in its entirety.

2. The United States of America is the only country in the world that has a "first to invent" law. All other countries use "first to file" laws where the first party to file a patent application on a new invention will generally be the one that gets the patent. In the United States the assertion that one is "first to invent" must be supported by solid, verifiable records of the date of invention, followed by diligent pursuit. Verifiable records may be by: 1) records that are understood and witnessed by unbiased third parties that can and will testify about them in court, 2) contemporaneously prepared (or collected) business records that are believable and that you (or their preparers) can believably swear by, and 3) records that are held by an unimpeachable source (such as the now-ended disclosure program at the U.S. PTO.

3. The Patent Examiner has cited U.S. Published Patent Application 2002/0039990 by Stanton, filed December 7, 2000, published April 4, 2002 as prior art under §103(a) against the patentability of my claimed invention.

4. As I understand it, 35 U.S.C. §103(a) states that "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title." In turning to 35 U.S.C. §102(e), an Applicant is entitled to a patent unless the invention was "(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

granted on an application for patent by another filed in the United States before the invention by the applicant for patent.

5. However, 35 U.S.C. §102(e), would not apply to my invention as compared to Stanton for the purpose of establishing a priority date. Only section of 35 U.S.C. §102(e)(1) is relevant to the present situation, and section (1) specifies the *publication of the application*. As I have repeatedly explained, Stanton is not an application for patent that was *published* by another in the US *before Applicant's actual invention*. Stanton was not published until April 4, 2002, well *AFTER* my constructive date of invention based upon the effective filing February 21, 2001. Consequently, Stanton is not proper prior art as applied to my invention.

6. Moreover, since 35 U.S.C. §102(e) applies to my actual date of invention, I have submitted several documents to the U.S. Patent Office to establish my actual date of invention, which was well before even the December 7, 2000 filing date of the Stanton application. These letters, although submitted to the Patent Office in 1999 and 2000, under the "disclosure" option at the PTO discussed as option (3) above (which was discontinued in February 2007) have not been considered by the Examiner in this case. The disclosure program was established by the Patent Office for exactly this purpose, to permit inventors to place their inventions on record until a formal application could be filed. See link at http://www.uspto.gov/web/offices/pac/disdo.html.

7. Attached are copies of letters submitted to Box DD of the U.S. PTO on July 25, 1999 and November 12, 2000, describing my conception of improvements to my earlier filed patent application, USSN 09/449,178, filed Nov. 24, 1999, now U.S. Pat. No. 6,219,674. These letters (presently in unsigned form, which will be followed by copies of the signed letters), clearly demonstrate that my actual date of invention antedates the December 7, 2000 filing date of the Stanton application, as well as my continued diligence. Copies of these letters may be available to the Examiner at the PTO wherever records of the disclosure program are maintained. Moreover, discussions were held with my attorneys *prior to December 7, 2000* to discuss my invention and patent strategy. *Of note* the filing of provisional application 60/270,697 (filed very shortly after December 7, 2000).

8. Consequently, Stanton is not proper prior art against my present invention, since the actual date of my invention is shown to have preceded the filing date of Stanton's cited published patent application.

9. I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: August 1, 2008 ; John B Classen

J. Barthelow Classen, M.D., M.B.A.
Classen Immunotherapies
6517 Montrose Avenue
Baltimore, MD 21212
Tel: (410) 377-4549 Fax: (410) 377-8526
E mail: classen@vaccines.net http://vaccines.net

July 25, 1999

Box DD
Assistant Commissioner for Patents
Washington, DC 20231

Dear Sir or Madam:

I am writing to describe methods and system for developing proprietary safety information pertaining to medical products. The method and systems relies on the gathering of data pertaining to adverse events associated with medical products including drugs, biologicals, and medical devices. This data can be obtained electronically through the screeing of insurance and other databases. An company can buy access to the database from insurance companies, hospitals, managed care organizations, third party database companies, and public health departments for example.

The data can be collected using the ICD and other disease codes on admission, discharge, pharmaceutical sales, or physician visit records. The frequency of adverse events such as death, hospitalization, office vists, disability, abnormal lab tests can be found in the individuals receiving the medical product in question and compared to rate in the person before receiving the medical product or in persons of similar characteristics. Subgroup analysis can be performed to determine specific high risk groups who may be at increased risk of having an adverse event. Subgroups can include persons with similar characteristics such as sex, age , weight, height, per cent body fat, race, genes, pregnancy, additional medical problems, use of additional medical products, past medical history, family history, social history, occupation, use of al cohol, tobacco, recreational drugs, history of abnormal lab tests such as EKG, chest xray, liver function test, kidney function test.

Optionally efficacy data can be collected too. The benefit of the medical product in certain subgroups can be measured looking at the the frequency of the intended benefit,(ie decreased death, stroke, kidney failure ect). Benefits can include reductions in costs where the costs can include cost of the medical product, medical expesnes and lost productivity. By using the data from the risks and benefits one can determine the risk/benefit for persons in the particular subgroup. This information can be stratified for different utilization of the medical product for example dose of a drug or biologic, frequency of use of a device, or setting of an implantable device such as a pacemaker.

Targeted searches can be performed. For example if it is discovered from one database that those reciving a medical product are increased risk for dying of liver fasilure at a ceretain dose or when taking the drug in combination then one can attempt to verify the findings using a second database. Results can also be confirmed in animals or by prospective clinical trials in humans.

A proprietary database can be created containing information on a particular product including adverse events and optionally risk benefits and cost benefits. The data can be crossed with a database of knowledge already accumulated on the product. Sources of prior adverse events can include package inserts, the Physician's Desk Reference, The Merk Manual, data from regulatory agencies such as the FDA, and published litterature found on databases such as Medline. New findings on adverse reactions can thus be determined . The new knowledge can include new adverse events, specific frequency of adverse events, drug interactions, side effects in specific subgroups as mentioned above.

The system can be used to generate data for patents or possibly copyrights. Patents can be obtained for package labeling warning about adverse events. The system can also create documents for licensing of the proprietary information so that information can be licensed to manufacturers or other interested parties. Manufacturers not willing to license the technology can be forced to remove their product from the market if they do not adequately pertray the risks of their products. Ideally the system will contain information on products from several different manufacturers and include information on several different classes of products.

The information can be processed at a single module or in different areas using seperate modules such as personal computers or workstations. The modules can be connected via a modem, one or more servers, a central computer or other system designe to link computers or other processing machines. Ideally the information should be transfered digitaly between modules as in computer files. Alternatively it can be converted into analog as in the form of a modem transmission along standard telphone lines. The data can be printed out and either rekeyed or scanned back into digital data for use in a different module. Ideally all printed material should be printed from the system using printers however labels and pakage inserts can be manually type faced using a traditional type faced printer.

This system can also be utilized to develop proprietary safety information on products unrelated to the medical fields since the manufacturers are also required to include safety information. Non limiting examples could include food, food additives, chemicals, tobacco, alcohol, mechanical devices.

Sincerely

J. Barthelow Classen, M.D., M.B.A.
Classen Immunotherapies
6517 Montrose Avenue
Baltimore, MD 21212
Tel: (410) 377-4549 Fax: (410) 377-8526
E mail: classen@vaccines.net http://vaccines.net

November 12, 2000

Box DD
Assistant Commissioner for Patents
Washington, DC 20231

Dear Sir or Madam:

I have submitted a patent application pertaining to business methods on or around November 24th, 1999. I have included a few improvements which I intend to patent where these improvements pertain to this invention.

1. The first invention pertains to comparing the incidence of the new adverse event to that in a control group where the control group received a competing technology. When the system is looking at a therapeutic modality such as a drug the improvement is using controls which receive an competing therapeutic modality such as a drug with treats the same disease or a surgical procedure that treats the same disease. If the system is looking at a fuel then the control group would be exposed to a competing fuel such as oil vs. coal vs. natural gas versus electricity. In the like manner the system could compare those exposed to a oil based paint to a latex based paint as a non limiting example.

2. An related improvement is that the manufacturer, distributor or marketer of a product could include a licensing agreement with the sale of the product which states the product can only be used for certain purposes. The license would exclude the use of the product to determine new proprietary uses, where the new uses are discovered by looking for new adverse events. The licensing agreement could be similar to that seen with software where the breaking of a seal indicates one agrees with the contract. The licensing agreement could accompany the product or alternatively could be signed prior to the delivery of a product to a purchaser, end user, distributor etc.

3. An related improvement is a claim that the system of the invention can not be used to try to discredit the existence of the one new adverse event, or the utility of the one new proprietary use. This will prevent competitors from trying to block the proprietary new use, product etc.

Sincerely